Citation:

Fischler GE, Fuls JL, Dail EW, Duran MH, Rodgers ND, Waggoner AL. Effect of hand wash agents on controlling the transmission of pathogenic bacteria from hands to food. *J Food Prot.* 2007 Dec; 70(12): 2,873-2,877.

PubMed ID: 18095447

Study Design:

Randomized controlled experiments

Class:

A - Click here for explanation of classification scheme.

Research Design and Implementation Rating:

NEUTRAL: See Research Design and Implementation Criteria Checklist below.

Research Purpose:

- To evaluate the effectiveness of a commercially available antimicrobial hand wash (antimicrobial hand soap) containing triclosan (0.46%, wt/wt) as the active antimicrobial ingredient and a plain, non-medicated hand wash (plain soap) at reducing bacteria on hands following a 15- or 30-second hand wash
- To look at the subsequent transfer of the surviving *E. coli* and *S. flexneri* from the washed hands to a ready-to-eat food item, freshly cut cantaloupe melon balls.

Inclusion Criteria:

- A series of four experiments were performed (A through D)
- Seven to 13 subjects older than 18 years were randomly assigned

Exclusion Criteria:

None.

Description of Study Protocol:

Recruitment

- Seven to 13 subjects older than 18 years were randomly assigned to receive a single hand washing treatment with either antimicrobial hand soap (0.46% triclosan, Dial Complete Antibacterial Foaming Hand Wash) or a plain soap (Kiss My Face Self-foaming Liquid Soap) following hand contamination with *S. flexneri* or *E. coli* as part of a series of four experiments were performed (A through D)
- Informed consent was obtained, and the experiments were conducted in accordance with Good Clinical Practice Regulations.

Design

A series of four experiments were performed (A through D):

- Seven to 13 subjects older than 18 years were randomly assigned to receive a single hand washing treatment with either antimicrobial hand soap (0.46% triclosan, Dial Complete Antibacterial Foaming Hand Wash) or a plain soap (Kiss My Face Self-foaming Liquid Soap) following hand contamination with *S. flexneri* or *E. coli*. The same two hand soaps were used in all four experiments.
- The method used in these studies was a modification (an improved hand contamination procedure and an evaluation of the transfer of bacteria to food following hand washing) of the standard American Society for Testing and Materials test method E1174 evaluation of health care personnel hand wash formulations
- In each of the experiments, subjects were asked to refrain from using any antimicrobial products for at least four days prior to test day
- On test day, subjects performed a conditioning wash to remove dirt and bacteria from their hands and to familiarize themselves with the hand wash procedure. Hands were then challenged with bacteria by a modification of the standard method (American Society for Testing and Materials E1174) in which only the palmar surfaces of the hands were contaminated.
- In experiments A and B, the subjects' hands were contaminated with *E. coli*, and in experiments C and D, their hands were contaminated with *S. flexneri*
- In all experiments, a baseline sampling was taken following the first hand contamination step. This was done to determine the total number of organisms contaminating the hands. Following baseline sampling, the subjects performed a second conditioning wash and then a repetition of the hand contamination step. They were then instructed to perform a hand washing treatment specific to each type of hand soap tested.
- Following hand treatment with the prescribed test material, the subjects were asked to handle the food; cantaloupe melon balls that had been prepared prior to test day. The outside of the melon was cleaned with 70% isopropyl alcohol to reduce the potential of cross-contamination to the inside of the melon during slicing and melon ball preparation.
- Four 2.2cm melon balls per subject were prepared with a sterile melon ball scoop. The four melon balls were placed into a sterile specimen cup and refrigerated at 5°C until test day.
- The melon balls were brought to room temperature prior to use. The melon balls were dispensed into the subjects' dominant hand. Subjects rolled the balls for 15±2 seconds in their palms with the thumb and fingers. After 15 seconds, the melon balls were placed directly into a sterile stomacher bag. 20ml of sterile neutralizing stripping solution was added to the bag, and the melon balls were pulverized for one minute at 260 rpm with a stomacher.
- Immediately after handling the food, the subjects' non-dominant hand was sampled by the previously described sampling method. Bacterial enumeration was performed by standard microbiological plating methods.

Intervention

- Patients were instructed to perform a hand washing treatment specific to each type of hand soap tested
- The soap was dispensed into the subjects' cupped dry palm of one hand and then spread over the entire surface of the hands, including the backs of the hands and between the fingers and the lower one-third of the forearm
- For the antimicrobial hand soap, two pumps (3g) of soap were dispensed, and four pumps (3g) were used for the plain soap

- In experiments A and B, the soap was lathered vigorously over the hands for 15±2 seconds, and in experiments C and D, the soap was lathered for 30±2 seconds
- After the timed wash, hands were rinsed under running tap water tempered to 40±2°C for 30 seconds.

Statistical Analysis

- Bacteria counts (CFU per hand) were converted to log counts. The right- and left-hand bacteria log counts were averaged and comparisons were made between baseline, wash treatment and transfer counts.
- Log bacteria reduction was calculated by the mean average baseline minus the mean average recovery from the treatment group
- The number of bacteria transferred to the melon balls was calculated by multiplying the CFU per milliliter by 40 to obtain the total bacteria count per 20g or four melon balls (5g per ball). If a subject dropped one of the melon balls, an adjustment was made to the multiplier.
- The CFU per 20g of melon balls was converted to log counts and the mean average log recovered bacteria count was calculated
- Paired two-tailed statistical analysis was performed on the wash treatment and transfer counts.

Data Collection Summary:

Timing of Measurements
After 15 seconds of hand contact with the melon balls.

Dependent Variables

Effectiveness was determined by evaluating the difference between the baseline and post-wash bacteria recovery counts, and the difference in the transfer of bacteria to food was calculated with the number of bacteria per 20 g of melon (about four melon balls) recovered.

Independent Variables

- Hand washing treatment with either antimicrobial hand soap (0.46% triclosan, Dial Complete Antibacterial Foaming Hand Wash) or a plain soap (Kiss My Face Self-foaming Liquid Soap)
- Hand washing time: In experiments A and B, the soap was lathered vigorously over the hands for 15±2 seconds; in experiments C and D, the soap was lathered for 30±2 seconds)
- Bacteria tested (either *S. flexneri* or *E. coli*).

Description of Actual Data Sample:

- *Initial N:* Seven to 13 subjects
- *Attrition (final N):* N varied between seven and 13 in experiments A to D
- *Age:* Older than 18 years (otherwise not reported)
- *Location:* Scottsdale, Arizona.

Summary of Results:

Key Findings

- In all four experiments, the antimicrobial hand soap was significantly better than plain soap and water at eliminating bacteria on hands and subsequently at reducing the transfer of bacteria from hands to food
- The antimicrobial soap achieved 3.84- and 3.29-log reductions vs. *E. coli* after a 15-second wash and 3.31- and 2.83-log reductions vs. *S. flexneri* after a 30-second wash, whereas the plain soap failed to achieve a 2-log reduction against either organism, regardless of the wash time
- Significantly fewer bacteria were transferred to the melon balls from hands washed with antimicrobial soap than from hands washed with plain soap
- The average log bacteria recovery from the melon balls handled by hands treated with antimicrobial hand soap was 2.00, 2.36, 1.97 and 2.27 log
- Melon balls handled with plain soap-treated hands had more than 3-log bacteria in all four experiments. This was a statistically significant difference ($P<0.001$, two-tailed) of more than 1.25 log compared with the antimicrobial hand wash-handled melons.
- The number of bacteria that were transferred to the melon balls following hand washing for both 15 and 30 seconds with the antimicrobial soap was statistically less than plain soap and water.

Author Conclusion:

- The data demonstrate there is a greater potential to reduce the transmission and acquisition of disease through the use of an antimicrobial hand wash than through the use of plain soap
- The number of bacteria that were transferred to the melon balls following hand washing for both 15 and 30 seconds with the antimicrobial soap was not only statistically less than plain soap and water, but more importantly, this two- to 2.2-log dose obtained for the antimicrobial soap is at the lower end of the dose-response range for *S. flexneri,* and would be anticipated to result in significantly fewer cases of infection than the 3-log dose obtained for the plain soap.

Reviewer Comments:

- *Neither subjects nor researchers were blinded to soap use*
- *Dial Corporation Clinical Studies Department assisted in the clinical aspects of the study*
- *Small sample size.*

Research Design and Implementation Criteria Checklist: Primary Research

Relevance Questions

1.	Would implementing the studied intervention or procedure (if found successful) result in improved outcomes for the patients/clients/population group? (Not Applicable for some epidemiological studies)	Yes
2.	Did the authors study an outcome (dependent variable) or topic that the patients/clients/population group would care about?	Yes

3.	Is the focus of the intervention or procedure (independent variable) or topic of study a common issue of concern to nutrition or dietetics practice?	Yes
4.	Is the intervention or procedure feasible? (NA for some epidemiological studies)	Yes

Validity Questions

1.	**Was the research question clearly stated?**	Yes
1.1.	Was (were) the specific intervention(s) or procedure(s) [independent variable(s)] identified?	Yes
1.2.	Was (were) the outcome(s) [dependent variable(s)] clearly indicated?	Yes
1.3.	Were the target population and setting specified?	Yes
2.	**Was the selection of study subjects/patients free from bias?**	Yes
2.1.	Were inclusion/exclusion criteria specified (e.g., risk, point in disease progression, diagnostic or prognosis criteria), and with sufficient detail and without omitting criteria critical to the study?	Yes
2.2.	Were criteria applied equally to all study groups?	???
2.3.	Were health, demographics, and other characteristics of subjects described?	N/A
2.4.	Were the subjects/patients a representative sample of the relevant population?	N/A
3.	**Were study groups comparable?**	Yes
3.1.	Was the method of assigning subjects/patients to groups described and unbiased? (Method of randomization identified if RCT)	???
3.2.	Were distribution of disease status, prognostic factors, and other factors (e.g., demographics) similar across study groups at baseline?	N/A
3.3.	Were concurrent controls used? (Concurrent preferred over historical controls.)	Yes
3.4.	If cohort study or cross-sectional study, were groups comparable on important confounding factors and/or were preexisting differences accounted for by using appropriate adjustments in statistical analysis?	N/A
3.5.	If case control or cross-sectional study, were potential confounding factors comparable for cases and controls? (If case series or trial with subjects serving as own control, this criterion is not applicable. Criterion may not be applicable in some cross-sectional studies.)	N/A

3.6.	If diagnostic test, was there an independent blind comparison with an appropriate reference standard (e.g., "gold standard")?	N/A
4.	**Was method of handling withdrawals described?**	Yes
4.1.	Were follow-up methods described and the same for all groups?	Yes
4.2.	Was the number, characteristics of withdrawals (i.e., dropouts, lost to follow up, attrition rate) and/or response rate (cross-sectional studies) described for each group? (Follow up goal for a strong study is 80%.)	Yes
4.3.	Were all enrolled subjects/patients (in the original sample) accounted for?	Yes
4.4.	Were reasons for withdrawals similar across groups?	N/A
4.5.	If diagnostic test, was decision to perform reference test not dependent on results of test under study?	N/A
5.	**Was blinding used to prevent introduction of bias?**	No
5.1.	In intervention study, were subjects, clinicians/practitioners, and investigators blinded to treatment group, as appropriate?	No
5.2.	Were data collectors blinded for outcomes assessment? (If outcome is measured using an objective test, such as a lab value, this criterion is assumed to be met.)	No
5.3.	In cohort study or cross-sectional study, were measurements of outcomes and risk factors blinded?	N/A
5.4.	In case control study, was case definition explicit and case ascertainment not influenced by exposure status?	N/A
5.5.	In diagnostic study, were test results blinded to patient history and other test results?	N/A
6.	**Were intervention/therapeutic regimens/exposure factor or procedure and any comparison(s) described in detail? Were interveningfactors described?**	Yes
6.1.	In RCT or other intervention trial, were protocols described for all regimens studied?	Yes
6.2.	In observational study, were interventions, study settings, and clinicians/provider described?	N/A
6.3.	Was the intensity and duration of the intervention or exposure factor sufficient to produce a meaningful effect?	Yes
6.4.	Was the amount of exposure and, if relevant, subject/patient compliance measured?	Yes
6.5.	Were co-interventions (e.g., ancillary treatments, other therapies) described?	Yes
6.6.	Were extra or unplanned treatments described?	N/A

6.7.	Was the information for 6.4, 6.5, and 6.6 assessed the same way for all groups?	Yes
6.8.	In diagnostic study, were details of test administration and replication sufficient?	N/A
7.	**Were outcomes clearly defined and the measurements valid and reliable?**	Yes
7.1.	Were primary and secondary endpoints described and relevant to the question?	Yes
7.2.	Were nutrition measures appropriate to question and outcomes of concern?	Yes
7.3.	Was the period of follow-up long enough for important outcome(s) to occur?	Yes
7.4.	Were the observations and measurements based on standard, valid, and reliable data collection instruments/tests/procedures?	Yes
7.5.	Was the measurement of effect at an appropriate level of precision?	Yes
7.6.	Were other factors accounted for (measured) that could affect outcomes?	Yes
7.7.	Were the measurements conducted consistently across groups?	Yes
8.	**Was the statistical analysis appropriate for the study design and type of outcome indicators?**	Yes
8.1.	Were statistical analyses adequately described and the results reported appropriately?	Yes
8.2.	Were correct statistical tests used and assumptions of test not violated?	Yes
8.3.	Were statistics reported with levels of significance and/or confidence intervals?	Yes
8.4.	Was "intent to treat" analysis of outcomes done (and as appropriate, was there an analysis of outcomes for those maximally exposed or a dose-response analysis)?	Yes
8.5.	Were adequate adjustments made for effects of confounding factors that might have affected the outcomes (e.g., multivariate analyses)?	N/A
8.6.	Was clinical significance as well as statistical significance reported?	Yes
8.7.	If negative findings, was a power calculation reported to address type 2 error?	N/A
9.	**Are conclusions supported by results with biases and limitations taken into consideration?**	No
9.1.	Is there a discussion of findings?	Yes
9.2.	Are biases and study limitations identified and discussed?	No
10.	**Is bias due to study's funding or sponsorship unlikely?**	No

10.1.	Were sources of funding and investigators' affiliations described?	No
10.2.	Was the study free from apparent conflict of interest?	No